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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,575	07/05/2001	Jan Zur Megede	PP01631.102 (CHIR-1631/03)	1709
7590	06/02/2005			EXAMINER
Anne S. Dollard CHIRON CORPORATION Intellectual Property - R440 P.O. Box 8097 Emeryville, CA 94662-8097			PARKIN, JEFFREY S	
			ART UNIT	PAPER NUMBER
			1648	
DATE MAILED: 06/02/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/899,575	MEGEDE ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Jeffrey S. Parkin, Ph.D.	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

#### A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 10 March 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-97 is/are pending in the application.
- 4a) Of the above claim(s) 1-37,40-44 and 46-97 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 38, ~~39+~~ and 45 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |





### Detailed Office Action

#### *Status of the Claims*

Applicants' election with traverse of Group II (claims 2-6 and 38-46) and SEQ ID NO.: 120 in the communication dated 10 March, 2005, is acknowledged. Applicants are reminded that only claims 38, 39, and 45 are directed toward SEQ ID NO.: 120. The traversal only appears to extend to the assertion that there are several independent and distinct inventions within Group II (e.g., SEQ ID NOS.: 46, 47, 49, ...) and not to the other restriction groups. The traversal is based upon the premise that it would not constitute and undue burden to examine all of the sequences concomitantly. It was additionally argued that up to ten sequences may be examined according to § 803.04 of the M.P.E.P. Applicants' arguments have been carefully considered but are not deemed to be persuasive. First, applicants are reminded that § 803.04 of the M.P.E.P. is only a guideline and not legally binding. Moreover, the "ten" nucleotide sequence policy evolved in response to the large number of nucleotide sequences being disclosed in SPDI applications, of which this application is clearly not a member. Thus, the "ten" nucleotide sequence guideline is not applicable. Second, two criteria currently exist for the determination of proper restriction requirements (see M.P.E.P. § 803):

- (1) The inventions must be independent (see M.P.E.P. § 802.01, § 806.04, § 808.01) or distinct as claimed (see M.P.E.P. § 806.05); and,
- (2) There must be a serious burden on the examiner if restriction is not required (see M.P.E.P. § 803.02, § 806.04(a)-(j), § 808.01(a), and § 808.02).

Establishment of *prima facie* evidence for a serious burden requires the demonstration, by appropriate explanation, of either separate classification, separate status in the art, or a different field of

search as defined in M.P.E.P. § 808.02. The basis for the restriction requirement was clearly set forth in the restriction requirement mailed 05 January, 2005. Each nucleotide sequence is directed toward structurally different envelope glycoproteins and would require separate searches. Applicants further asserted that the various envelope sequences are closely related, but failed to provide any diagrams or sequence alignments demonstrating this fact. Accordingly, the **requirement is still deemed to be proper and is therefore made FINAL**. Claims 1-37, 40-44, and 46-97 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

**37 C.F.R. § 1.98**

The information disclosure statement filed 09 June, 2003, fails to comply with the provisions of 37 C.F.R. § 1.97, 1.98 and M.P.E.P. § 609. The IDS lists 64 patent documents, 128 foreign patent documents, and 154 non-patent literature documents. Because the excessive number of references would constitute an undue burden on the examiner, they will not be considered unless a statement identifying their relevance to the claimed invention is provided. Accordingly, the IDS has been placed in the application file, but the information referred to therein has not been considered as to the merits.

**35 U.S.C. § 112, First Paragraph**

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38, 39, and 45 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in

the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). *University of Rochester v. G. D. Searle & Co., Inc.*, 358 F.3d 916, 69 U.S.P.Q.2d 1886 (C.A.F.C. 2004). The claims are broadly directed toward expression cassettes comprising polynucleotides that are at least 90% genetically related to the parent sequence (SEQ ID NO.: 120). The claims do not limit the polynucleotide to any particular length or corresponding region of SEQ ID NO.: 120.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc., v. Mahurkar*, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116. The issue raised in this application is whether the original application provides adequate support for the broadly claimed genus of nucleic acids. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the biomolecule of interest. *In re Bell*, 991 F.2d

781, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993). *In re Deuel*, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995). A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1995). The court noted in this decision that a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not reasonably lead those skilled in the art to any particular species.

An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. For some biomolecules, examples of identifying characteristics include a nucleotide or amino acid sequence, chemical structure, binding affinity, binding specificity, and molecular weight. The written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. Without such a correlation, the capability to recognize or understand the structure from the mere recitation of function and minimal structure is highly unlikely. In the latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 U.S.P.Q.2d 1398, 1404, 1406

(Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998). In re Wilder, 736 F.2d 1516, 1521, 222 U.S.P.Q. 369, 372-3 (Fed. Cir. 1984). Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

The parent polynucleotide sequence (SEQ ID NO.: 120) encodes a modified HIV-1 recombinant envelope glycoprotein. The sequence is 1,986 nucleotides in length and encodes a glycoprotein just less than 876 aa. Thus, the parent nucleotide sequence is a relatively large molecule. The claims do not limit the polynucleotide sequence to any particular length. Thus, the claimed composition could correspond to the full-length nucleotide sequence or any portion thereof. The disclosure fails to provide sufficient guidance pertaining to the molecular determinants modulating the structural and functional properties of the modified HIV-1 envelope. Thus, the skilled artisan can not readily envisage any particular nucleotide sequence variant. Clearly, the situation in this application is analogous to *Fujikawa v. Wattanasin* wherein the court clearly stated that a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not reasonably lead those skilled in the art to any particular species. Absent further guidance from applicants, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing.

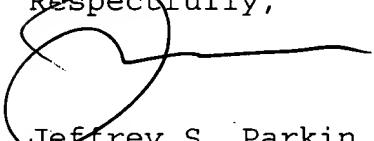
#### Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, James C. Housel, can be reached at (571) 272-0902. Direct general status inquiries to the Technology Center

1600 receptionist at (571) 272-1600. Formal communications may be submitted through the official facsimile number which is (703) 872-9306. Hand-carried formal communications should be directed toward the customer window located in Crystal Plaza Two, 2011 South Clark Place, Arlington, VA. Applicants are directed toward the O.G. Notice for further guidance. 1280 O.G. 681. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,



Jeffrey S. Parkin, Ph.D.  
Primary Examiner  
Art Unit 1648

30 May, 2005